UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte ROGER COLEMAN, JANICE AU-YOUNG, OLGA BANDMAN, and JEFFREY J. SEILHAMER

Appeal No. 2005-1422
Application No. 09/997,522

ON BRIEF[1]

Before SCHEINER, ADAMS, and GRIMES, Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 3-7, 9, 10, 12, 13, 57 and 58. Claims 1, 14-16, 28, 29, 46, 47 and 56, the only remaining pending claims, are withdrawn from consideration as drawn to non-elected subject matter.

Claims 3, 4, 6, 9 and 12 are illustrative of the subject matter on appeal and are reproduced below:

3. An isolated polynucleotide encoding a polypeptide selected from the group consisting of:
   a) a polypeptide comprising the amino acid sequence of SEQ ID NO:2,

[1] Appellants waived their request for oral hearing. Paper received September 13, 2005. Accordingly, we considered this appeal on Brief.

b) a polypeptide comprising a naturally occurring amino acid sequence, wherein the naturally occurring amino acid sequence differs from the amino acid sequence of SEQ ID NO:2 by a substitution of one amino acid residue and/or an insertion of 1-5 amino acid residues and/or a deletion of 1-5 amino acid residues,
c) a thrombin-binding fragment of a polypeptide, wherein the polypeptide has the amino acid sequence of SEQ ID NO:2, and
d) an immunogenic fragment of a polypeptide having the amino acid sequence of SEQ ID NO:2, wherein said fragment comprises at least 13 contiguous amino acid residues of SEQ ID NO:2.

4. An isolated polynucleotide of claim 3 encoding a polypeptide comprising the amino acid sequence of SEQ ID NO:2.

6. A recombinant polynucleotide comprising a promoter sequence operably linked to a polynucleotide of claim 3.

9. A method of producing a polypeptide encoded by a polynucleotide of claim 3, the method comprising:
a) culturing a cell under conditions wherein the polypeptide is expressed, and wherein said cell is transformed with a recombinant polynucleotide, and said recombinant polynucleotide comprises a promoter sequence operably linked to a polynucleotide of claim 3, and
b) recovering the polypeptide so expressed.

12. An isolated polynucleotide selected from the group consisting of:
a) a polynucleotide comprising the polynucleotide sequence of SEQ ID NO: 1,
b) a polynucleotide comprising a naturally occurring human variant of the polynucleotide sequence of SEQ ID NO: 1,
c) a polynucleotide complementary to a polynucleotide of a),
d) a polynucleotide complementary to a polynucleotide of b), and
e) an RNA equivalent of a)-d).

The references relied upon by the examiner are:

Coleman el al. ('597)	5,686,597	Nov. 11, 1997
Coleman et al. ('633)	5,869,633	Feb. 9, 1999

Smith, et al. (Smith), "The challenges of genome sequence annotation or 'The devil is in the details,'" Nature Biotechnology, Vol. 15, pp. 1222-1223 (November 1997)

Doerks, et al. (Doerks), "Protein annotation: detective work for function prediction," Trends in Genetics, Vol 14, No. 6, pp. 248-250 (June 1998)

(Soukhanov), pp. 646 and 956 (A. H. Soukhanov, et al. eds., New Riverside University Dictionary. The Riverside Publishing Co.) (1988)

Brenner, "Errors in genome annotation," Trends in Genetics, Vol. 15, No. 4, p. 132 (April 1999)

Bork et al. (Bork I), "Go hunting in sequence databases but watch out for the traps," Trends in Genetics, Vol. 12, No. 10, pp. 425-427 (1996)

Bork (Bork II), "Powers and pitfalls in sequence analysis: the 70% hurdle," Genome Research, Vol. 10, pp. 398-400 (2000)

Skolnick, et al. (Skolnick), "From genes to protein structure and function:novel applications of computational approaches in the genomic era," Trends in Biotech, Vol. 18, No. 1, pp. 34-39 (2000)

GROUNDS OF REJECTION

Claims 4, 5, and 57 stand rejected under 35 U.S.C. § 101 as claiming the same invention as claims 1 and 3 of U.S. Patent No. 5,686,597.

Claims 3, 4, 5, 12, 13, and 57 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,869,633.

Claims 3, 4, 5, 12, 13, and 57 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 3 of U.S. Patent No. 5,686,597.

Claim 6 stands rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 2 of U.S. Patent No. 5,686,597.

Claims 9 and 10 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 6 of U.S. Patent No. 5,686,597.

Claims 6 and 7 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4 and 5 of U.S. Patent No. 5,686,597.

Claims 3, 6, 7, 9, 12, 13, and 58 stand rejected under the written description provision of 35 U.S.C. § 112, first paragraph.

Claims 3, 6, 7, 9, 12, 13, and 58 stand rejected under the enablement provision of 35 U.S.C. § 112, first paragraph.[2]

Claims 3-7, 9, 10, 12, 13, 57, and 58 stand rejected under 35 U.S.C. § 101 as lacking utility and § 112, first paragraph, for lack of enablement based on the finding of lack of utility.

We affirm the double patenting rejection under 35 U.S.C. § 101, the rejections under the judicially created doctrine of obviousness-type double patenting, and the rejection under the written description provision of 35 U.S.C. § 112, first paragraph. Having disposed of claims 3, 6, 7, 9, 12, 13, and 58 under the written description provision of 35 U.S.C. § 112, first paragraph, we do not reach the merits of the rejection of these claims under the enablement provision of 35 U.S.C. § 112, first paragraph. We reverse the utility rejections under 35 U.S.C. § 101 and § 112, first paragraph.

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[2] In response to appellants' arguments in the Brief, the examiner withdrew claims 4, 5, 10, and 57 from this ground of rejection. Supplemental Answer, page 15.

DISCUSSION

Statutory Double Patenting:

Claims 4, 5 and 57 stand rejected under 35 U.S.C. § 101 as claiming the same invention as claims 1 and 3 of U.S. Patent No. 5,686,597. According to appellants (Brief, page 5), "[a]ll of the claims on appeal are grouped together," with regard to this ground of rejection. Since all claims stand or fall together, we limit our discussion to representative claim 4. Claims 5 and 57 will stand or fall together with claim 4. In re Young, 927 F.2d 588, 590, 18 USPQ2d 1089, 1091 (Fed. Cir. 1991).

Claim 4 of the present application depends from and further limits independent claim 3 to an isolated polynucleotide that encodes a polypeptide comprising the amino acid sequence of SEQ ID NO:2. Claim 1 of the '597 patent is drawn to "[a]n isolated and purified polynucleotide encoding a thrombin receptor homolog (TRH) comprising the amino acid sequence of SEQ ID NO:2." According to appellants' specification (page 1), the instant application is a divisional application of the '597 patent. Therefore, the amino acid sequence of SEQ ID NO:2 of the instant application is the same as SEQ ID NO:2 of the '597 patent. Accordingly, the polynucleotides set forth in claim 4 of the instant application, and claim 1 of the '597 patent are the same.

Appellants' only argument is that the polynucleotide set forth in claim 4 of the instant application is "isolated," whereas the polynucleotide set forth in claim 1 of the '597 patent is "isolated and purified." Brief, page 45. According to

appellants (Brief, page 46), "the terms 'purified' and 'isolated' are not exactly the same, and [therefore] the scope of the claims at issue differ...."

With reference to Soukhanov, the examiner finds (Supplemental Answer, page 20),

> Purified is a relative term, and only means 'removed from its natural source', unless otherwise defined in the specification. [Soukhanov] ... defines "isolate" as (1) to set apart from a group or whole. (2) to place in quarantine. (3) to obtain in an uncombined form. (4) to render free of external influence. [Soukhanov] ... defined "purify" as (1) to rid of impurities. (2) to rid of foreign or unwanted elements. Neither "purified" nor "isolated" specifically mean homogeneous. Therefore, unless otherwise defined, 'isolated' means the same as 'purified' [sic], and 'isolated and purified' [sic] is merely redundant.

According to the examiner (id.), the specification fails to define either term.

Since the specification is the same for the instant application as well as the '597 patent, we understand the examiner's assertion to be that the terms are not defined as they relate to a polynucleotide that encodes a polypeptide comprising the amino acid sequence of SEQ ID NO:2 in either the instant specification or the '597 patent. In response, appellants argue (Reply Brief, page 14, emphasis added), "the term 'purified' would encompass the separation of a pre-existing object from other materials while the term 'isolated' could additionally encompass the production of an object in an environment separate from other materials." While appellants may have intended their claim to be read as set forth above, appellants fail to direct our attention to any portion of their specification, and we find none, that supports their interpretation of the claim. 35 U.S.C. § 112, second paragraph puts the burden of precise claim drafting squarely on the applicant. In re Morris, 127 F.3d 1048, 1056, 44 USPQ2d 1023,

1029 (Fed. Cir. 1997). The problem in this case, as in Morris[3], is that appellant failed to make their intended meaning explicitly clear.

Accordingly, we find no error in the examiner's interpretation of the terms "isolated" and "purified" on this record. Therefore, we affirm the rejection of claim 4 under 35 U.S.C. § 101 as claiming the same invention as claims 1 and 3 of U.S. Patent No. 5,686,597. As discussed supra claims 5 and 57 fall together with claim 4.

Obviousness-type Double Patenting:

Claims 3, 4, 5, 12, 13 and 57:

Claims 3, 4, 5, 12, 13 and 57 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,869,633. Appellants acquiesce to this rejection and assert that a Terminal Disclaimer will be filed upon an indication of allowable subject matter. Brief, page 46. Accordingly, we affirm the rejection of claims 3, 4, 5, 12, 13 and 57 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,869,633.

Claims 3, 4, 5, 12, 13 and 57:

Claims 3, 4, 5, 12, 13 and 57 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 3 of U.S. Patent No. 5,686,597. Appellants acquiesce to this rejection and

[3] In re Morris, 127 F.3d at 1056, 44 USPQ2d at 1029.

assert that a Terminal Disclaimer will be filed upon an indication of allowable subject matter. Brief, page 46. Accordingly, we affirm the rejection of claims 3, 4, 5, 12, 13 and 57 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 3 of U.S. Patent No. 5,686,597.

Claim 6:

Claim 6 stands rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 2 of U.S. Patent No. 5,686,597. Appellants acquiesce to this rejection and assert that a Terminal Disclaimer will be filed upon an indication of allowable subject matter. Brief, page 47. Accordingly, we affirm the rejection of claim 6 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 2 of U.S. Patent No. 5,686,597.

Claims 9 and 10:

Claims 9 and 10 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 6 of U.S. Patent No. 5,686,597. Appellants acquiesce to this rejection and assert that a Terminal Disclaimer will be filed upon an indication of allowable subject matter. Brief, page 47. Accordingly, we affirm the rejection of claims 9 and 10 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 6 of U.S. Patent No. 5,686,597.

Claims 6 and 7:

Claims 6 and 7 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4 and 5 of U.S. Patent No. 5,686,597. Appellants acquiesce to this rejection and assert that a Terminal Disclaimer will be filed upon an indication of allowable subject matter. Brief, page 47. Accordingly, we affirm the rejection of claims 6 and 7 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4 and 5 of U.S. Patent No. 5,686,597.

Written Description:

Claims 3, 6, 7, 9, 12, 13 and 58 stand rejected under the written description provision of 35 U.S.C. § 112, first paragraph. According to appellants (Brief, page 5), "[a]ll of the claims on appeal are grouped together," with regard to this ground of rejection. Since all claims stand or fall together, we limit our discussion to representative independent claim 12. Claims 3, 6, 7, 9, 13 and 58 will stand or fall together with claim 12. In re Young, 927 F.2d 588, 590, 18 USPQ2d 1089, 1091 (Fed. Cir. 1991).

According to the examiner (Supplemental Answer, page 7), a polynucleotide encompassed by generic claim 12 which is a "naturally occurring human variant[ ] of SEQ ID NO: 1 ... would have one or more nucleic acid substitutions, deletions, insertions and/or additions to the polynucleotide of SEQ ID NO: 1...." According to appellants' specification (page 4), "nucleotide

sequence, SEQ ID NO: 1, ... encodes a novel human thrombin receptor homolog (TRH), SEQ ID NO:2."

While claim 12 is drawn, inter alia, to "a naturally occurring human variant of the polynucleotide sequence of SEQ ID NO: 1," appellants' specification does not define the term "naturally occurring human variant" in the context of a TRH polypeptide, or a polynucleotide.[4] With regard to a polypeptide, appellants' specification discloses that a "'[n]aturally occurring TRH' [polypeptide] refers to TRHs produced by human cells that have not been genetically engineered and specifically contemplates various TRHs arising from post-translational modifications of the polypeptide including but not limited to acetylation, carboxylation, glycosylation, phosphorylation, lipidation and acylation." Specification, page 5. We note that appellants do not define a naturally occurring TRH polypeptide as a variant. Instead, appellants define polypeptide variants as "recombinant polypeptide variants." See specification, page 5, a "'[r]ecombinant polypeptide variant' refers to any polypeptide having the activity of the TRH polypeptide and differing from naturally occurring TRHs by amino acid insertions, deletions, and substitutions created using recombinant DNA techniques." On reflection, appellants' specification does not identify, or disclose a naturally occurring human variant of a TRH polypeptide.

[4] We recognize appellants' assertion (Brief, page 36) that "variants of SEQ ID NO:1 and SEQ ID NO:2 are described in the specification at, for example, page 4, lines 30-32; page 5, lines 22-25; page 5, line 30 to page 6, line 11; page 7, lines 17-23; and page 8, lines 14-29." None of these sections of appellants' specification, however, provide a description of a "naturally occurring human variant of the polynucleotide sequence of SEQ ID NO: 1" as required by claim 12, part b.

The same is true of the polynucleotide of claim 12. Appellants define polynucleotide variants as "recombinant nucleotide variants," not naturally occurring human variants. See specification, page 7,

> "[r]ecombinant nucleotide variants" encoding T7Gs may be synthesized or selected by making use of the "redundancy" in the genetic code. Various codon substitutions, such as the silent changes which produce specific restriction sites, may be introduced to optimize cloning into a plasmid or viral vector or to increase expression in a particular prokaryotic or eukaryotic system. Codon usage-specific mutations may also be introduced or chimeras containing the domains of related peptides added to test or modify the properties of any part of the polypeptide, particularly to change ligand-binding affinities, interchain affinities, or degradation/turnover rate.

We note with interest that appellants' definition of "recombinant nucleotide variants" defines the variants as encoding "T7Gs." According to appellants' specification (page 1), "[t]he thrombin receptor[5] is a G-protein coupled seven transmembrane receptor (T7G) which is present on platelets, endothelial cells, fibroblasts, mesangial cells, neural cells and smooth muscle cells." G-protein coupled seven transmembrane receptors (T7Gs), however, encompass more than the thrombin receptor.[6] According to appellants' specification (page 2),

> The thrombin receptor is classified with the nonneurokinin T7G receptors which include many glycoprotein hormone receptors such as those for luteinizing hormone (LH) and follicle stimulating hormone (FSH). They have very long N-termini, bind a common ligand structural motif with low affinity to activate the receptor, and rely on the N-termini and extracellular loops to impart high affinity and specificity....

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[5] According to appellants' specification (page 4), SEQ ID NO: 1 as set forth in claim 12 "encodes a novel human thrombin receptor homolog (TRH)."

[6] According to appellants (Brief, page 11), "T7G proteins as a class are well known as proteins which transmit signals across plasma membranes in response to specific stimuli."

> They are related to other T7Gs by their seven hydrophobic domains which span the plasma membrane and form a bundle of antiparallel α helices.

On reflection, appellants' specification does not identify, or disclose a naturally occurring human variant of the polynucleotide sequence of SEQ ID NO: 1. At best, appellants' specification suggests that the claimed variant may encode a member of the large family of T7G receptors, one of which is encoded by the polynucleotide of SEQ ID NO: 1.

Against this backdrop, we note that the examiner finds (Supplemental Answer, page 7),

> the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. The specification and claims do not provide any guidance as to what changes are made to SEQ ID NO:1 ... to be considered a naturally occurring human variant.... Structural features that could distinguish compounds in the genus from others in the polynucleotide ... class are missing from the disclosure. No common structural attributes identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, SEQ ID NO: 1 ... alone ... [is] insufficient to describe the genus.

In response, appellants assert (Brief, page 37), "[v]ariants of SEQ ID NO: 1 and SEQ ID NO:2 are described in the specification at, for example, page 4, lines 30-32; page 5, lines 22-25; page 5, line 30 to page 6, line 11; page 7, lines 17-23; and page 8, lines 14-29." With regard to variants of a polynucleotide sequence, as discussed above, the cited portions of the specification do not refer to "naturally occurring human variants," but instead address "recombinant nucleotide variants." In addition, as defined in appellants' specification at page

7, lines 17-23, the "recombinant nucleotide variants" encode T7Gs generally. There is no specific requirement in appellants' definition of nucleotide variants that requires the nucleotide sequence to encode a human thrombin receptor or homolog thereof. Accordingly, we disagree with appellants' assertion (Brief, page 37), "[o]ne of ordinary skill in the art would recognize polynucleotide sequences which are TRH[7]-encoding variants of SEQ ID NO:1, having codons which vary from those of SEQ ID NO:1." There is no requirement in appellants' claim 12 that a "naturally occurring human variant of the polynucleotide sequence of SEQ ID NO: 1" encode a thrombin receptor homolog.

Appellants also assert (Brief, page 42), "[t]he subject matter of the present claims is defined in terms of the chemical structure of SEQ ID NO:1...." In our opinion, this assertion fails to take into account the full scope of claim 12. Claim 12, part b is drawn to a "naturally occurring human variant of the polynucleotide sequence of SEQ ID NO: 1." As defined by the portion of the specification appellants rely upon for support, variant polynucleotides encode T7Gs. Specification, page 7, lines 17-23. In this regard, we note that appellants admit (Brief, page 43), "[t]he present application is directed, inter alia, to polynucleotides encoding G-protein coupled seven transmembrane receptor proteins (T7Gs), including polynucleotides encoding thrombin receptor homologs related to the amino acid sequence of SEQ ID NO:2." Claim 12 does not require any relationship with SEQ ID NO:2, or that the nucleotide variant actually encode

[7] According to appellants' specification (page 5), "[a]s used herein, TRH, refers to thrombin receptor homologs, naturally occurring TRHs and active fragments thereof, which have essentially the amino acid sequence shown in SEQ ID NO:2."

a T7G. In all, we find no requirement in claim 12 that any particular "common structural feature" be present in the claimed polynucleotide variant.[8]

Further, assuming arguendo, claim 12 was limited to T7G receptors, as discussed above T7Gs encompass a large genus of receptors, which according to appellants' specification (page 2), "are related to other T7Gs by their seven hydrophobic domains which span the plasma membrane and form a bundle of antiparallel α helices." However, contrary to appellants' assertion (Brief, page 42), there is no evidence on this record that the genus of T7G receptors can be defined in terms of the chemical structure of SEQ ID NO:1 and/or SEQ ID NO:2. To that end, there is no evidence on this record that the entire genus encompassed by claim 12 can be defined in terms of the chemical structure of SEQ ID NO: 1. In this regard, there is no requirement in claim 12 that the seven hydrophobic domains used to characterize T7Gs be retained in the claimed variant. Accordingly, contrary to appellants' assertion (Brief, page 43), claim 12 does "describe a genus which could be characterized as 'highly variant.'"

"A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." University of California v. Eli Lilly and Co.,

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[8] In this regard, we disagree with appellants' assertion (Reply Brief, page 12), "[t]he claimed polynucleotide variants are described in terms of their common structural features (e.g., differing from the amino acid sequence of SEQ ID NO:2 by a substitution of one amino acid residue and/or an insertion of 1-5 amino acid residues and/or a deletion of 1-5 amino acid residues), and in terms of other features such as occurrence in nature." We note, however, that with the exception of its "occurrence in nature," the variant of claim 12, part b does not require any of the other "common structural features" asserted by appellants. Regarding the requirement that the variant occur in nature, we note that numerous polynucleotides are naturally occurring, and exhibit no common

119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997), provides the appropriate analysis. The claims in Lilly were directed generically to vertebrate or mammalian insulin cDNAs. See id. at 1567, 43 USPQ2d at 1405. The court held that a structural description of a rat cDNA was not an adequate description of these broader classes of cDNAs, because a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." Id. (bracketed material in original).

The Lilly court explained that

> a generic statement such as ... 'mammalian insulin cDNA,' without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus.

Id. at 1568, 43 USPQ2d at 1406. Finally, the Lilly court set out exemplary ways in which a genus of cDNAs could be described:

> A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus.

Id.

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structural features. There is simply no evidence on this record, or requirement in claim 12, that the claimed variant exhibit any "common structural feature" in common with SEQ ID NO:1.

Our appellate reviewing court revisited the issue of describing DNA. See Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956, 964, 63 USPQ2d 1609, 1613 (Fed. Cir. 2002). The Enzo court held that a claimed DNA could be described without, necessarily, disclosing its structure. The court adopted the standard that "the written description requirement can be met by 'show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics ... i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.'" See id. at 1324, 63 USPQ2d at 1613 (emphasis omitted, ellipsis and bracketed material in original).

Our appellate review court has also noted that "Eli Lilly did not hold that all functional descriptions of genetic material necessarily fail as a matter of law to meet the written description requirement; rather, the requirement may be satisfied if in the knowledge of the art the disclosed function is sufficiently correlated to a particular, known structure." Amgen, Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1332, 65 USPQ2d 1385, 1398 (Fed. Cir. 2003).

As discussed above, there is no requirement in claim 12, or evidence on this record, that the claimed polynucleotide variant exhibit a particular "common structural feature" or function. On reflection, it is our opinion that appellants have failed to adequately describe the genus of polynucleotides encompassed by claim 12. Accordingly, we affirm the rejection of claim 12 under the written

description provision of 35 U.S.C. § 112, first paragraph. As discussed supra claims 3, 6, 7, 9, 13 and 58 fall together with claim 12.

Enablement:

Claims 3, 6, 7, 9, 12, 13, and 58 stand rejected under the enablement provision of 35 U.S.C. § 112, first paragraph. Having disposed of claims 3, 6, 7, 9, 12, 13, and 58 under the written description provision of 35 U.S.C. § 112, first paragraph, we do not reach the merits of the rejection of these claims under the enablement provision of 35 U.S.C. § 112, first paragraph.

Utility:

Claims 3-7, 9, 10, 12, 13, 57 and 58 stand rejected under 35 U.S.C. § 101 as lacking utility and § 112, first paragraph, for lack of enablement based on the finding of lack of utility.[9]

The initial burden of showing lack of utility is on the examiner. See Brana, 51 F.3d at 1566, 34 USPQ2d at 1441. See also In re Langer, 503 F.2d 1380, 1391, 183 USPQ 288, 297 (CCPA 1974) ("[A] specification which contains a disclosure of utility which corresponds in scope to the subject matter sought to be patented must be taken as sufficient to satisfy the utility requirement of § 101 for the entire claimed subject matter unless there is reason for one skilled in the

[9] The examiner rejected the claims under both 35 U.S.C. § 101 and 35 U.S.C. § 112, first paragraph. However the rejection for nonenablement was presented simply as a corollary of the finding of lack of utility. See Supplemental Answer, page 5. Therefore, although we discuss only the § 101 rejection, our conclusion also applies to the rejection under the enablement provision of 35 U.S.C. § 112, first paragraph.

art to question the objective truth of the statement of utility or its scope."). In this case, that means that the burden is on the examiner to show that those skilled in the art would doubt the objective truth of the specification's statement that the claimed nucleic acids encode a thrombin receptor homolog.

On this record, appellants point out (Brief, page 13),

> [t]he instant application is a continuation of, and claims priority to, Coleman (U.S. Ser. No. 09/643,383....), which is a divisional of, and claims priority to Coleman et al. (U.S. Ser. No. 09/217,101, [now United States Patent No. 6,143,870 ('870)[10]] ...), which is a divisional of, and claims priority to, Coleman et al. (U.S. Ser. No. 08/911,320, [now United States Patent No. 5,869,633 ('633)] ...), which is a divisional of, and claims priority to, Coleman et al. (U.S. Ser. No. 08/467,125, [now United States Patent No. 5,686,597 ('597)]....

As appellants point out (Brief, page 13), but for the correction of typographical errors and reformatting, the instant specification is essentially identical to the specifications of Application Nos. 09/217,101, 08/911,320 and 08/467,125 now respectively, United States Patent Nos. 6,143,870, 5,869,633, and 5,686,597. For clarity, we reproduce representative claims from each patent:

The '870 patent;

1. A purified polypeptide comprising the amino acid sequence of SEQ ID NO[:] 2.

The '633 patent;

1. An isolated and purified polynucleotide which is complementary to a polyncleotide encoding the polypeptide having the amino acid sequence of SEQ ID NO: 2.

The '597 patent;

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[10] We note that the examiner of record in this appeal was also the examiner of record on the '870 patent.

1. An isolated and purified polynucleotide encoding a thrombin receptor homolog (TRH) comprising the amino acid sequence of SEQ ID NO: 2.

3. The polynucleotide of claim 1 comprising a recombinant DNA molecule whose nucleotide sequence is shown as SEQ ID NO[:] 1.

Since the specifications of the three patents and the instant specification are the same, SEQ ID NOs: 1 and 2 as well as the utilities presented are expected to be the same. The claims of an issued patent are entitled to a presumption of validity. 35 U.S.C. § 282. This includes a presumption that the claims define an invention that meets the requirements of 35 U.S.C. § 101. Thus, the examiner in this case must meet a heightened burden of proof, since showing that the instant claims lack utility would apparently mean showing that claims issued in the '870, '633, and '597 patents also lack utility.

On this record, the examiner finds (Supplemental Answer, page 3),

> [i]t is clear from the instant specification that the claimed receptor is what is termed an "orphan receptor" in the art. The instant application does not disclose the biological role of the protein encoded for by the claimed polynucleotide, or its significance. Applicants disclose in the specification that this receptor is believed to be a thrombin receptor. However, the basis that the receptor encoded for by the polynucleotide of the present invention is only known to be homologous to thrombin receptors (page 2, lines 21-26 of the specification) is not predictive of a use.

In support of this rejection the examiner relies on Skolnick, Bork I, Bork II, Doerks, Smith, and Brenner, to support his position. Collectively, these references show two things: (1) comparing a new protein with existing sequences does not always accurately predict the function of the new protein and (2) minor changes in amino acid sequence can result in major changes in a

protein's function. The examiner characterizes these references as showing "that function cannot be predicted based solely on structural similarity to a protein found in the sequence databases." Supplemental Answer, page 4.

In our view, the references cited by the examiner show that sequence similarity does not always accurately predict function, because of potential inaccuracies in the sequence databases and because function does not necessarily follow from a limited amount of similarity. However, the evidence does not support a per se rule that structural similarity by itself cannot accurately predict function. Each case must be considered on its own facts. On this record the examiner makes no attempt to address the structural similarity of the claimed nucleic acid sequences with the human thrombin receptor or to establish any evidence tending to demonstrate that appellants' specification is inaccurate in its disclosure that "[t]his invention relates to nucleic acid and amino acid sequences of a new human thrombin receptor homology...."

Accordingly, we find that the examiner failed to meet his evidentiary burden of establishing that appellants' disclosure fails to establish a utility for the claimed invention. We therefore reverse the rejection of claims 3-7, 9, 10, 12, 13, 57 and 58 stand rejected under 35 U.S.C. § 101 as lacking utility and § 112, first paragraph, for lack of enablement based on the finding of lack of utility.

SUMMARY

We affirm:

The rejection of claims 4, 5, and 57 under 35 U.S.C. § 101 as claiming the same invention as claims 1 and 3 of U.S. Patent No. 5,686,597;

The rejection of claims 3, 4, 5, 12, 13, and 57 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,869,633.

The rejection of claims 3, 4, 5, 12, 13, and 57 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 3 of U.S. Patent No. 5,686,597.

The rejection of claim 6 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 2 of U.S. Patent No. 5,686,597.

The rejection of claims 9 and 10 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 6 of U.S. Patent No. 5,686,597.

The rejection of claims 6 and 7 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4 and 5 of U.S. Patent No. 5,686,597.

The rejection of claims 3, 6, 7, 9, 12, 13, and 58 under 35 U.S.C. § 112, first paragraph, as the specification fails to provide an adequate written description of the claimed invention.

We do not reach the merits of:

The rejection of claims 3, 6, 7, 9, 12, 13, and 58 under the enablement provision of 35 U.S.C. § 112, first paragraph.

We reverse:

The rejection of claims 3-7, 9, 10, 12, 13, 57, and 58 under 35 U.S.C. § 101 as lacking utility and § 112, first paragraph, for lack of enablement based on the finding of lack of utility.

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

Toni R. Scheiner)
Administrative Patent Judge)
)
) BOARD OF PATENT
)
Donald E. Adams) APPEALS AND
Administrative Patent Judge)
) INTERFERENCES
)
Eric Grimes)
Administrative Patent Judge)

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